



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352

March 16, 2017

Mr. Glenn P. Sullivan  
Corporate Radiation Safety Officer  
Cardinal Health  
7000 Cardinal Place  
Dublin, OH 43017

Dear Mr. Sullivan:

We have completed our review of the decommissioning funding plan (DFP) and cost estimate dated March 3, 2016, you provided in support of the Xofigo<sup>®</sup> manufacturing facility (NRC License Number 34-32780-04MD). Based on our review, the DFP will require significant information to be acceptable.

Be advised that Title 10 of the *Code of Federal Regulations* (CFR) 30.35 (e) states that each decommissioning funding plan must be submitted for review and approval and must contain the following information:

- 1) A detailed cost estimate for decommissioning, in an amount reflecting:
  - (A) The cost of an independent contractor to perform all decommissioning activities;
  - (B) The cost of meeting the 10 CFR 20.1402 criteria for unrestricted use; however, if Cardinal Health cannot meet this criteria, you need to demonstrate your ability to meet the provisions of 10 CFR 20.1403 (restricted release), and base the cost estimate on satisfying 10 CFR 20.1403 criteria;
  - (C) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and
  - (D) An adequate contingency factor.
- 2) Identification of and justification for using the key assumptions contained in the decommissioning cost estimate (DCE);
- 3) A description of the method of assuring funds for decommissioning from 10 CFR 30.35 (f), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;
- 4) A certification from Cardinal Health that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and
- 5) A signed original of the financial instrument obtained to satisfy the requirements of paragraph 10 CFR 30.35(f).

We strongly encourage you to reference NUREG 1757, Vol 3, Rev 1. Section 3 as you prepare your DFP and supporting documentation. In addition, model language for a certification of financial assurance is presented in NUREG-1757, Vol 3, Rev 1 Appendix A, Section A.2.4. Please provide a separate certification of financial assurance as described in NUREG-1757, Vol 3, Rev 1 Appendix A. We have enclosed a sample "Certification of Financial Assurance" for your information.

**Please respond within 60 days and reference Control Number 590483 in your response.**

Be advised that further delays and failure to address significant deficiencies related to the financial assurance provided for licensed activities covered under NRC License Number 34-327800-04MD may potentially impact any expansion of activities covered under this license. If you have any questions, please contact Daniel Strohmeier at 630-829-9689 [daniel.strohmeier@nrc.gov](mailto:daniel.strohmeier@nrc.gov) or Jennifer L. Bishop at 630-829-9607 [jennifer.bishop@nrc.gov](mailto:jennifer.bishop@nrc.gov).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agency wide Documents Access Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

*/RA/*

Patricia J. Pelke, Chief  
Materials Licensing Branch  
Division of Nuclear Materials Safety

License No. 34-32780-04MD  
Docket No. 030-38867

Enclosure:  
Sample Certification of Financial Assurance

G. Sullivan

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Letter to Mr. Glenn Sullivan from Patricia Pelke dated March 16, 2017

SUBJECT: Cardinal Deficiency Letter

DISTRIBUTION:

Bryan Parker

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DATE	3/16/2017	3/15/2017	3/16/2017	

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#### A.2.4 Model Certification of Financial Assurance

### CERTIFICATION OF FINANCIAL ASSURANCE

Principal: *[Legal names and business address of licensee]*  
NRC license number, name, and address of the facility

Issued to: U.S. Nuclear Regulatory Commission

I certify that *[insert name of licensee]* is licensed to possess the following types of *[insert all that apply: "sealed sources or plated foils with a half-life greater than 120 days licensed under 10 CFR Part 30," "unsealed byproduct material with a half-life greater than 120 days licensed under 10 CFR Part 30," "source material in a readily dispersible form licensed under 10 CFR Part 40," "unsealed special nuclear material licensed under 10 CFR Part 70" and "spent nuclear fuel, high-level radioactive waste, and reactor-related greater than Class C waste licensed under 10 CFR Part 72"]* in the following amounts:

<u>Type of Material</u>	<u>Amount of Material</u>
<i>[List materials and quantities of materials noted above. For <b>byproduct materials</b> and <b>special nuclear materials</b>, list separately the type and amount of <b>each isotope</b> authorized by the license.]</i>	

I also certify that financial assurance in the amount of *[insert the total of all prescribed amounts calculated from Checklist 2 or the amount of the site-specific cost estimate, in U.S. dollars]* has been obtained for the purpose of decommissioning as prescribed by 10 CFR Part *[insert 30, 40, 70, or 72]*.

*[This paragraph is needed for a 10 CFR Part 72 licensee (10 CFR 72.30(e)(5)) only that qualifies to use an external sinking fund that is not coupled with another form of financial assurance.]* I also certify that *[insert name of licensee]* is qualified to use the assurance method of 10 CFR 72.30(e)(5) or 10 CFR 50.75(e)(1)(ii), and *[insert name of licensee]* either (1) recovers the total cost of decommissioning through rates established by "cost of service" or similar ratemaking regulation or (2) has a source of revenues for its external sinking fund that is a "non-bypassable charge," the total amount of which will provide funds needed for decommissioning. As of *[insert date]*, *[\$[insert dollar amount]]* has been collected for decommissioning. Therefore, *[\$[insert dollar amount]]* remains to be collected for decommissioning. The remaining funds needed for decommissioning will be collected *[insert frequency (i.e., monthly, semi-annually, annually)]* over the next *[insert time period]* in the amount of *[\$[insert dollar amount]]*.